REMARKS

Claims 1-14 and 32 have been canceled without prejudice to their merit. Applicant reserves the right to pursue the subject matter of Claims 1-14 in one or more continuing applications.

Claims 15-31, 33, and 34 are currently pending and under consideration. These claims have not been amended herein.

Rejection of Claims 1-8 and 32 under 35 U.S.C. §112, First Paragraph

This rejection has been rendered moot by cancellation of Claims 1-8 and 32.

Rejection of Claims 1-6 and 32 under 35 U.S.C. §112, Second Paragraph

This rejection has been rendered moot by cancellation of Claims 1-6 and 32.

Rejection of Claims 1 and 4-6 under 35 U.S.C. §102(b) over Neamatallah et al.

This rejection has been rendered moot by cancellation of Claims 1 and 4-6.

Rejection of Claims 1-13 and 15-34 under 35 U.S.C. §103(a) over Lee et al., Difco Manual, and Neamatallah et al.

This rejection as applied to Claims 1-13 and 32 has been rendered moot by cancellation of these claims.

This rejection as applied to Claims 15-31, 33, and 34 is traversed.

Each pending independent claim recites a *Listeria spp.*-selective medium that comprises nitrofurantoin. The prior art does not teach or suggest including nitrofurantoin in a *Listeria* growth medium. This position has been presented in Applicant's Response dated October 6, 2010 at the paragraph spanning pages 14-15 through the second full paragraph on page 15, the second full paragraph on page 16, and the second full paragraph on 17, and is elaborated herein.

Of the cited prior art, only Neamatallah et al. even mention nitrofurantoin. However, Neamatallah et al. do not teach a medium that **comprises** nitrofurantoin. Neamatallah et al. discuss nitrofurantoin only in the context of testing the sensitivity of *Listeria monocytogenes* to nitrofurantoin. However, Neamatallah et al. do not test the sensitivity by adding nitrofurantoin to a

Listeria growth medium. Rather, they test the sensitivity by growing *Listeria* on a nitrofurantoin-free growth agar (*i.e.*, *Listeria*-selective agar – Oxford formulation) and placing a nitrofurantoin-impregnated disc on *Listeria* colonies grown on the agar (Neamatallah et al. at paragraph spanning pages 230 and 231). Sensitivity to nitrofurantoin is determined by the presence of zones of colony clearing underneath the impregnated disc (Neamatallah et al. at paragraph spanning pages 230 and 231). While the nitrofurantoin-impregnated discs **contact** the *Listeria* colonies, the underlying agar does not **comprise** nitrofurantoin.[1] After assessing antibiotic sensitivity, Neamatallah et al. then proceed to generate several media that do **comprise** certain antibiotics. However, the only antibiotics included in such media are those to which *Listeria* demonstrates resistance: colistin sulphate, nalidixic acid, and sulphamethizole. Neamatallah et al. **do not** generate such a medium comprising nitrofurantoin (Neamatallah et al. at left-hand column on page 231 and paragraph spanning pages 231-232).

Thus, Neamatallah et al. do not teach a *Listeria* growth medium that comprises nitrofurantoin.

Furthermore, Neamatallah et al. provide no teachings to suggest modifying the media of Lee et al. and/or Difco Manual to include nitrofurantoin. Neamatallah et al. instead teach that ***Listeria monocytogenes* is sensitive to nitrofurantoin**. The Office has explicitly acknowledged this teaching by Neamatallah et al.: "Applicant's arguments regarding **sensitivity** to nitrofurantoin by *Listeria* are noted" (Office Action dated October 6, 2010 at fourth full paragraph on page 5). Thus, the teachings of Neamatallah et al. suggest that adding nitrofurantoin to the *Listeria* growth media of Lee et al. and/or Difco Manual would be detrimental because it would kill rather than facilitate growth of *Listeria*.

Against the teaching of sensitivity of *Listeria* to nitrofurantoin, Neamatallah et al. provide no teachings whatsoever to suggest adding nitrofurantoin to the *Listeria* growth media of Lee et al.

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[1] Exhibit A is an informational brochure for the antibiotic-impregnated discs from Mast Laboratories (Liverpool, UK) used by Neamatallah et al. The informational brochure states that each disc carries "6 or 8 antibiotic impregnated tips, each of which performs as a single susceptibility testing disc due to the **isolating hydrophobic barrier**" (see Exhibit A at "Description" on page 2; emphasis added). Thus, the nitrofurantoin in the impregnated disc is isolated from the *Listeria* growth agar by virtue of the hydrophobic barrier.

and/or Difco Manual. Taken as a whole, Neamatallah et al. therefore teach against adding nitrofurantoin to a *Listeria* growth medium such as those provided by Lee et al. and/or Difco Manual.

In sum, only Neamatallah et al. mention nitrofurantoin in the context of a *Listeria* growth medium. However, Neamatallah et al. neither teach nor suggest including nitrofurantoin in *Listeria* growth media, such as those provided by Lee et al. and/or Difco Manual.

In view of the foregoing, Applicant traverses the Office's position that "Neamatallah et al. adequately demonstrate that it is known in the art to add nitrofurantoin to selective media intended for the recovery and/or identification of *Listeria*" (Office action dated November 3, 2010 at fifth full paragraph on page 4). As is evident from the remarks above, Neamatallah et al. do not add nitrofurantoin to selective media intended for the recovery and/or identification of *Listeria* or teach any apparent benefits of doing so. The teachings of Neamatallah et al. instead teach away from adding nitrofurantoin to such media.

Applicant additionally traverses the Office's position that "it would have been obvious…to modify the composition of Lee et al. by adding nitrofurantoin as an additional selective tool, for the expected benefit of better selecting and identifying the dangerous pathogen *Listeria*" (*Id.* at first full paragraph on page 5). According to the teachings of Neamatallah et al, adding nitrofurantoin to the *Listeria monocytogenes* selective agar of Lee et al. would be detrimental because it would kill the very organism that Lee et al. are trying to recover. Thus, it would not be obvious to modify the composition of Lee et al. by adding nitrofurantoin as an additional selective tool.

Applicant additionally traverses the Office's position that "Neamatallah et al. use a **concentration** of 50 μg nitrofurantoin, but [do] not indicate whether it is per liter or per ml" (*Id.* at fourth full paragraph on page 5; emphasis added). Neamatallah et al. do not use a medium comprising nitrofurantoin in any concentration. The 50 μg described by Neamatallah et al. refers to the amount of nitrofurantoin contained in the disc. The nitrofurantoin is not included in the medium. The teaching of Neamatallah et al. regarding sensitivity of *Listeria* to nitrofurantoin is a general teaching and is not limited to any specific concentration. Therefore, in view of the teachings of Neamatallah et al., a practitioner in the art would not be motivated to add nitrofurantoin to a *Listeria* growth medium at any concentration.

In view of the foregoing, Neamatallah et al. does not provide any teaching or suggestion to include nitrofurantoin in the *Listeria* growth media of Lee et al. and/or Difco Manual. The present obviousness rejection is therefore improper. Withdrawal of this rejection is requested.

CONCLUSION

Applicant submits the application is in condition for allowance.

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I certify that this paper is being electronically submitted to the U.S. Patent and Trademark Office via the EFS-Web system on the following date:

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MASTRING-S™

The increase in susceptibility tests demanded of the laboratory led to an increase in time spent on performing these tests. MASTRING-S™ was developed as a solution to reducing technician time in processing the large number of tests that have to be performed daily. MASTRING-S™ is a convenient to use multiple tipped device which permits 6 or 8 single discs to be applied to an inoculated plate in one rapid easy movement.

Letter/number coding	▪ Allows individual customer specification and easy identification of antimicrobials
Easy to use	▪ Convenience in handling, allows the simultaneous application of the equivalent of 6 or 8 discs to a plate
Stock range	▪ Facilitates testing of Gram +ve, Gram –ve and Urine isolates
Impermeable hydrophobic barrier	▪ Localises drug ensuring round zones for easy interpretation
Free centre	▪ Permits use of additional disc if needed
Strict quality control	▪ Controlled to the same critical standards demanded of single discs
Colour coding	▪ Security of impregnation

Ex A

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Description

A ring device carrying 6 or 8 antibiotic impregnated tips, each of which performs as a single susceptibility testing disc due to the isolating hydrophobic barrier.

A stock range of different MASTRING-S™ is available (see separate list) but over 95% of MASTRING-S™ are manufactured to individual customer specifications.

In use

As with single discs all MASTRING-S™ should be stored at 2-8°C in their container when not in use and allowed to equilibrate to room temperature before being opened. Transference of the MASTRING-S™ to the medium is best performed with a flamed needle or forceps. It is important to ensure that the ring is in contact with the medium at all points.

MASTRING-S™ can be made available to suit all recommended techniques e.g. BSAC, CLSI. The 6 drug MASTRING-S™ was originally designed to suit the Stokes technique recommended by the Association of Clinical Pathologists (1966)[1]. Inoculation of test and control organisms is facilitated by use of the MAST rotary Plater (Order No. ROP 157).

MASTRING-S™ has also been shown to provide an efficient system for direct susceptibility testing of specimens such as urine[2].

Interpretation

Interpretation of zone sizes is appropriate to the method used and is as per that for single antibiotic susceptibility test discs.

Packaging

100 MASTRING-S™ are supplied in each container with a desiccant tablet.

References

1. Association of Clinical Pathologists *Broadsheet No 55* 1956: (Revised Dec. 1982)
2. Waterworth Pamela M, Del Piano M. *J Cin Pathol.* 1976; **29:** 179-184

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LIST OF STOCK RINGS

Systemic Gram Positive Rings

M13	1-8	
C	Chloramphenicol	25µg
E	Erythromycin	5µg
FC	Fusidic acid	10µg
OX	Oxacillin	5µg
NO	Novobiocin	5µg
PG	Penicillin G	1 unit
S	Streptomycin	10µg
T	Tetracycline	25µg

M5	1-6	
AP	Ampicillin	10µg
C	Chloramphenicol	25µg
PG	Penicillin G	1 unit
S	Streptomycin	10µg
ST	Sulphatriad	200µg
T	Tetracycline	25µg

Systemic Gram Negative Ring

M43	1-8	
PG	Penicillin G	1 unit
CD	Clindamycin	2µg
GM	Gentamicin	10µg
FC	Fusidic acid	10µg
E	Erythromycin	5µg
TM	Trimethoprim	1.25µg
SMX	Sulphamethoxazole	25µg
T	Tetracycline	10µg

M14	1-8	
AP	Ampicillin	10µg
KF	Cephalothin	5µg
CO	Colistin Sulphate	25µg
GM	Gentamicin	10µg
S	Streptomycin	10µg
ST	Sulphatriad	200µg
T	Tetracycline	25µg
TS	Cotrimoxazole	25µg

Urine Rings

M26	1-8	
AP	Ampicillin	25µg
C	Chloramphenicol	50µg
CO	Colistin sulphate	100µg
K	Kanamycin	30µg
NA	Nalidixic acid	30µg
NI	Nitrofurantoin	50µg
S	Streptomycin	25µg
T	Tetracycline	100µg

M27	1-8	
AP	Ampicillin	25µg
GM	Gentamicin	10µg
PY	Carbenicillin	100µg
NA	Nalidixic acid	30µg
NI	Nitrofurantoin	50µg
SM	Sulphamethizole	200µg
T	Tetracycline	100µg
TS	Cotrimoxazole	25µg

M51	1-8	
AP	Ampicillin	25µg
NI	Nitrofurantoin	50µg
AUG	Augmentin	30µg
CIP	Ciprofloxacin	5µg
NA	Nalidixic acid	30µg
TM	Trimethoprim	2.5µg
CFX	Cephalexin	30µg
GM	Gentamicin	10µg

N.B.
The majority of MASTRING-S™ supplied to customers are to their own specifications.